



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,670	07/17/2003	Anup Kumar Ray	RG/G-32603A	2065
1095	7590	03/07/2005	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			HUANG, EVELYN MEI	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/621,670

Applicant(s)

RAY ET AL.

Examiner

Evelyn Huang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8,9,11,12 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8, 9, 11, 12, 16-21 is/are allowed.
- 6) ☒ Claim(s) 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 8, 9, 11, 12, 14-21 are pending. Claims 1-6 have been canceled according to the amendment filed on 5-21-2004. Claims 7, 10, 13 have been canceled according to the amendment filed on 12-6-2004.

#### ***Claim Rejections - 35 USC § 112***

2. The rejection for Claims 10, 13, 16-21 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn because the amendment has obviated the rejection.

#### ***Claim Rejections - 35 USC § 103***

3. The rejection for Claims 7, 10, 13 under 35 U.S.C. 103(a) as being unpatentable over Villani (4659716, PTO-1449) in view of Hansen (5658899) and/or Strupczewski (4954503) and/or Congy (5290951) is rendered moot by the cancellation of these claims.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villani (4659716, PTO-1449) in view of Hansen (5658899) and/or Strupczewski (4954503) and/or Congy (5290951).

Villani discloses the antihistaminic descarbonylethoxyloratadine and its pharmaceutically acceptable salts, such as furmarate, for treating allergic reactions (column 26, claim 3; column 1).

While Villani does not specifically describe the hemifurmarate as in the instant, it is well recognized in the pharmaceutical art that hemifurmarate is a pharmaceutically acceptable salt for compounds of diverse structures, as exemplified by Hansen (column 3, Example 1), by Strupczewski (column 10, Table II; columns 20-21, Examples 11-12) and by Congy (columns 17-18, Example 12; columns 21-22, Table 2, compound 56). Furthermore, Hansen specifically teaches that reproducible polymorphic crystalline hemifumarate may be derived from fumaric acid in ethanol (column 3, Example 1).

At the time of the invention, one of ordinary skill in the art would be motivated to prepare the hemifumarate of Villain's descarbonylethoxyloratadine according to the teachings of Hansen Strupczewski and/or Congy with the reasonable expectation of obtaining an additional reproducible crystalline salt form of descarbonylethoxyloratadine useful for treating allergic reactions.

The use of instant polymorph form 1 or form 2 to treat allergic reaction is identical to the use of the above obvious descarbonylethoxyloratadine hemifumarate in the treatment of allergic reactions for the following reasons. In the *in vivo* physiological situation (which is mostly aqueous), the crystalline polymorph form 1 or form 2 having a certain X-ray diffraction pattern would no longer exist and thus become the same as the above obvious desloratadine hemifumarate.

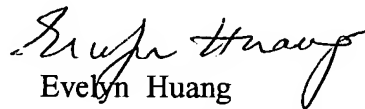
***Allowable Subject Matter***

5. Claims 8, 9, 11, 12, 16-21 are allowed for reasons of record.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

Art Unit: 1625

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Evelyn Huang

Primary Examiner

Art Unit 1625